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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/683,249	12/05/2001	Michael John Stephen Austin	S63.2-10014	8321
490	7590	07/19/2004		
VIDAS, ARRETT & STEINKRAUS, P.A. 6109 BLUE CIRCLE DRIVE SUITE 2000 MINNETONKA, MN 55343-9185			EXAMINER THALER, MICHAEL H	
			ART UNIT 3731	PAPER NUMBER

DATE MAILED: 07/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/683,249

Applicant(s)AUSTIN, MICHAEL JOHN
STEPHEN**Examiner**

Michael Thaler

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 May 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28,30,33 and 36-38 is/are pending in the application.
- 4a) Of the above claim(s) 4,10-28,30 and 33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-9 and 36-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

The request to correct the inventorship of this nonprovisional application under 37 CFR 1.48(a) is deficient because it lacks the written consent of any assignee of one of the originally named inventors.

Claims 4, 10-28, 30 and 33 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 6.

Claim 38 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no basis in the original disclosure for the limitation that the self-expanding cells are capable of self-expansion without expansion of the balloon expandable cells. In other words, the original disclosure nowhere indicates that the self-expanding cells expand prior to the expansion of the balloon expandable cells by the balloon.

Claims 1-3, 5-7, 9, 36 and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Vonesh et al. (WO

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00/33770). Vonesh et al., in figure 9, disclose a first balloon expandable segment (e.g. section 56 at the extreme left side of the figure), a second balloon expandable segment (e.g. section 56 at the middle of the figure) and a first self-expanding segment (e.g. the section 58 between the first and second balloon expandable segments). The balloon expandable segments may be not self-expanding as indicated on page 17, lines 5-9. As to claim 2, the sections 56 at the extreme left and right sides of the figure may be considered to be the claimed first and second balloon expandable segments while the two sections 58 may be considered to be the first and second self-expanding segments which are between the first and second balloon expandable segments. As to claim 3, the section 56 in the middle of the stent is considered to be the third balloon expandable segment. As to claim 5, the self-expanding cells are provided at intermediate islands 58 which are surrounded (on both sides) by balloon expandable material. As to claim 36, Vonesh et al. disclose a covering (the graft material) which is inherently protective. As to claim 38, the self-expanding cells are inherently capable of expansion, to some extent, without expansion of the balloon expandable cells.

Claims 8, 37 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vonesh et al. (WO 00/33770). As to

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claims 8 and 37, Vonesh et al., in the figure 9 embodiment, fail to disclose more balloon expandable cells than self-expandable cells. However, Vonesh et al., in other embodiments (e.g. figures 6 and 8) teach that the balloon expandable sections 56 may extend for a longer axial distance than the self-expandable sections 58. This arrangement has the advantage of providing a specific flow characteristic as described on page 17, lines 3-9. It would have been obvious to lengthen the balloon expandable sections 56 in the figure 9 embodiment so that it too would have this advantage. As to claim 38, assuming *arguendo* that the self-expanding cells are not inherently capable of expansion, to some extent, without expansion of the balloon expandable cells, it would have been obvious to make them so in order to make initial placement of the stent easy to accomplish which advantage is generally taught by Vonesh et al. in col. 8, lines 22-25.

Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Vrba (6,168,621). Vrba, in the embodiment described in col. 3, lines 11-12, discloses a first balloon expandable segment 30 and a first self-expanding segment 32 wherein the self-expanding cells are capable of self-expansion independently of the balloon expandable cells (col. 2, lines 23-26). Vrba, in this embodiment, fails to disclose a second

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balloon expandable segment. However, Vrba teaches that the examples given are intended to be illustrated only and not exhausted (col. 3, lines 13-14 and col. 2, lines 50-53). Further, Vrba, in the embodiment of figures 9-10 teaches that one branch 32 may be self expanding while the other branch 34 may be balloon expanding. This arrangement has the self-evident advantage of enabling immediate expansion of one branch (the self expanding branch) while permitting precise and limited expansion of the other branch (the balloon expanding branch). It would have been obvious to make one of the branches 32, 34 of in the embodiment described in col. 3, lines 11-12, self-expanding and one branch balloon expanding so that this embodiment too would have this advantage. With this modification, the stent would have each end constructed of balloon expandable material as claimed.

Applicant's arguments filed May 7, 2004 have been fully considered but they are not persuasive. As to the rejection of claim 38 under 35 U.S.C. 112, first paragraph, some of the self-expanding cells are surrounded on all sides by balloon expanding (i.e. non-self expanding) cells. Thus, without expansion of the balloon expandable cells, any expansion of the self-expanding cells must be caused by an expansion force which is large enough to expand and deform the material of the surrounding balloon

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expanding cells. The original disclosure nowhere indicates that the expanding force of the self-expanding cells is sufficient to permit their expansion without expansion of the balloon expandable cells. As to the rejections based upon Vonesh et al., this reference discloses that the balloon expandable segments may be not self-expanding noting the phrase "segments that are not self-expanding" on page 17, lines 5-9.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael

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Thaler whose telephone number is (703) 308-2981. The examiner can normally be reached Monday to Friday.

The fax phone number for the organization where this application or proceeding is assigned is (703)872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0858.

mht
7/14/04



MICHAEL THALER
PRIMARY EXAMINER
ART UNIT 3731